



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,588	10/02/2003	Jingrui Wu	38-15(52578)C	7647
27161	7590	12/29/2005	EXAMINER KUMAR, VINOD	
MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/678,588

Applicant(s)

WU ET AL.

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 07, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/01/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-13 and SEQ ID NO: 8 in the paper filed on November 7, 2005 is acknowledged.

Applicant's arguments are directed to the requirement to choose one sequence for examination. Applicants arguments filed on November 7, 2005 have been fully considered but they are not persuasive. Applicants urge the election of nucleic acid sequence is improper, since the identified sequences have a unique property of improving yield in a crop of transgenic plant grown under water stress deficit conditions as supported in specification (page 1, lines 4-6, second paragraph, response to office action).

The examiner maintains that due to variation in nucleic acid sequences (SEQ ID NOs: 2, 3, 6, 7, 8, 9 or 10), the art search for the different sequences are not coextensive but are highly divergent, and would impose an undue search burden, if done together. Claims 1-7 with elected SEQ ID NO: 8 are examined in this office action. SEQ ID NOs: 2, 3, 6, 7, 9 and 10 and claims 8-13, which encompass SEQ ID NO: 10, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Non-elected subject matter should be cancelled. This restriction is made FINAL.

Priority

2. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if

applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). The priority statement on line 9-10 of page 1 should be at the top of the page. The filing dates of the priority documents should also be recited.

Appropriate action is required.

3. ***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449 is attached to the instant Office action.

Specification

4. The disclosure is objected to because of the following informalities:

The use of the trademark "MS-Windows" on page 1 and line 6 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

On page 9 and lines 2 and 3, page 10 and line 20 and page 11 and line 4: U.S. patent serial number is cited. The status, abandoned or issued should also be recited. If issued, the U.S. Patent Number should be recited.

Claim Objections

5. Claims 6 and 7 are objected to because of the following informalities:

Claims require the article, --A—to be inserted at the beginning.

The term --plant—needs to be inserted in line 1 after “maize” in claim 6 and “soybean” in claim 7.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 5, 6 and 7 in part (b) and line 1, the recitation “ a consensus amino acid sequence of SEQ ID NO: 8” render claims indefinite. The article “a” makes it unclear whether the reference can be any sequence within SEQ ID NO: 8, or it is all of SEQ ID NO: 8. Applicants are suggested to change “a” to --the--.

Appropriate correction/clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1638

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method for improving yield in a crop exposed to water deficit by introducing into the genome of a plant a recombinant DNA construct expressing a gene which encodes a Hap3 protein having amino acid sequence as defined in SEQ ID NO: 8, or wherein water-deficit tolerant, transgenic, hybrid maize comprising said recombinant DNA construct expresses the said gene.

The specification describes transgenic corn and a method of producing said transgenic corn transformed with a gene encoding Hap3 (SEQ ID NO: 2) that confers water-deficit tolerance. See example 1 on page 12. The specification also describes transgenic soybean transformed with a gene encoding Hap3 (SEQ ID NOs: 5, 6 or 7) that exhibited enhanced resistance to water deficit compared to wild type soybean plants. See examples 3 and 4 on pages 14 and 15.

Claim 1 and claims dependent therefrom encompass a recombinant DNA construct expressing a gene which encodes a Hap3 protein having an amino acid sequence of SEQ ID NO: 8, which is a consensus amino acid sequence of amino acids of the transcription factors of SEQ ID NOs: 2, 3, 6 and 7. The specification indicates a transgenic plant with increased tolerance to water deficit stress conditions was

Art Unit: 1638

produced (see page 12, page 14 and Example 4 on page 14). However, the data presented in Tables 1-3 on pages 13 and 14 does not indicate that the transgenic plant transformed with a recombinant DNA construct expressing a gene which encodes for Hap3 protein as defined in SEQ ID NO: 2 actually displayed water-deficit tolerance.

The difference in plant height of transgenic versus non-transgenic plant under water-deficit stress conditions is less than 1 cm, which does not appear statistically significant.

See Tables 1-3 on pages 13-14. Further more Example 2 on page 14 describes chlorophyll index of 42 in transgenic plant which is statistically insignificant with chlorophyll index of 40 in wild type. Example 2 on page 14 describes that transgenic plant are "likely" to produce more photosynthate, "likely" to have cooler leaf temperature and likely to maintain higher stomatal conductance compared to non-transgenic control. But there is no guidance about the values of these parameters in transgenic versus nontransgenic control grown in water deficit stress conditions. There is no indication that transgenic plants actually displayed these phenotypes.

Applicants describe that SEQ ID NO: 8 is an artificial consensus amino acid sequence of a common core region of amino acids of the SEQ ID NOs: 2, 3 and 6 (see page 4 and line 8 of specification) that were over-expressed in transgenic plant with the intent of producing water-deficit tolerant phenotype. However, specification does not describe a transgenic plant or a method of producing a transgenic plant expressing a Hap 3 protein comprising SEQ ID NO: 8 but otherwise having any amino acid sequence, wherein transgenic plant is water-deficit tolerant. Also, Applicants have not provided any working example of transgenic plant or a method of producing a

Art Unit: 1638

transgenic plant comprising introducing an amino acid sequence comprising SEQ ID NO: 8 into the genome of a plant to produce water deficit tolerant phenotype. It is important to note that SEQ ID NO: 8 is a consensus, altered and truncated version of SEQ ID NOs: 2, 3 and 6. It is well established that proteins with similar structure may have different functions. See Keskin et al. (Protein Science, 13:1043-1055, 2004). Besides, Thornton et al. (Nature structural Biology, structural genomics supplement, November 2000) teach that structural data may carry information about the biochemical function of the protein. Its biological role in the cell or organism is much more complex and actual experimentation is needed to elucidate actual biological function under *in vivo* conditions. Furthermore, Guo et al. (PNAS, 101: 9205-9210, 2004) teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as SEQ ID NO: 8 encompass more than a single amino acid changes of the polypeptides defined in SEQ ID NOs: 2, 3, 6 or 7. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine how to change a DNA construct comprising a gene which encodes an amino acid sequence SEQ ID NO: 8 and use them in making water-deficit tolerant transgenic plant. Neither the state of art nor Applicant provide guidance as to how inoperable embodiments can be readily eliminated other than random trial and error.

Furthermore, in the absence of structure-based function prediction analysis and subsequent experimentation through working examples of transgenic plant, seed or method of producing said transgenic plant with increased tolerance to water-deficit

Art Unit: 1638

stress conditions, undue experimentation would be required by a skilled artisan to produce such a transgenic plant or seed or use it in a method of producing such transgenic plant with increased water deficit tolerance comprising introducing a recombinant DNA construct expressing a gene which encodes SEQ ID NO: 8. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Thus it is reasonable to conclude that data presented in specification (See Tables 1-3 on pages 11-14) raises serious doubts whether transgenic plants described in examples 3 and 4 of specification were actually water-deficit tolerant. Furthermore, keeping in view lack of guidance on common core region, a basis for consensus sequence, it will be highly unpredictable to guess whether SEQ ID NO: 8 can actually be used in a method to produce water-deficit transgenic plant. Undue experimentation would be required by a skilled artisan to determine the sequences of SEQ ID NOs: 2, 3, 6 and 7 that can be altered to create an amino acid sequence comprising the consensus sequence SEQ ID NO: 8, and what to change them to, without affecting the ability to produce desired phenotype upon over-expressing in a transgenic plant.

Given the breadth of the claims encompassing, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use of claimed invention.

7. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

Art Unit: 1638

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for improving yield in a crop exposed to water deficit by introducing into the genome of a plant a recombinant DNA construct expressing a gene which encodes a Hap3 protein having amino acid sequence as defined in SEQ ID NO: 8, or wherein water-deficit tolerant, transgenic, hybrid maize comprising said recombinant DNA construct expresses the said gene.

The specification describes transgenic corn and a method of producing said transgenic corn transformed with a gene encoding Hap3 (SEQ ID NO: 2) that confers water-deficit tolerance. See example 1 on page 12. The specification also describes transgenic soybean transformed with a gene encoding Hap3 (SEQ ID NOs: 5, 6 or 7) that exhibited enhanced resistance to water deficit compared to wild type soybean plants. See examples 3 and 4 on pages 14 and 15.

The claims encompass a recombinant DNA construct comprising a protein that has any amino acid sequence and the amino acid sequence of SEQ ID NO: 8, and which retains the ability to produce a water-deficit tolerant phenotype upon over-expressing in a transgenic plant. However specification only describes transgenic plant or a method of producing said transgenic plant upon over-expressing full length and unaltered SEQ ID NOs: 2, 5, 6 or 7. The specification does not disclose and correlate structures of different species of genus Hap3 protein having an amino acid sequence identical to a consensus sequence of SEQ ID NO: 8.

Furthermore, instant claims are directed to a Hpa3 protein having an amino acid sequence identical to SEQ ID NO: 8. The claims encompass mutants and allelic variants of *Hpa3* and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. Amino acid sequences comprising SEQ ID NO: 8 are not representative of other sequences encompassed by the claims. There are insufficient relevant identifying characteristics to allow one skilled in the art to determine such other sequences, or even other Hap3, from another plant species or an organism.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Conclusion

No claims are allowed.

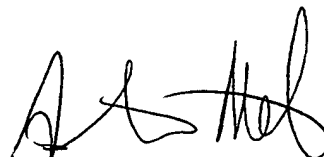
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

Art Unit: 1638

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 01, 2005



ASHWIN D. MENTA, PH.D.
PRIMARY EXAMINER